

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

Claim 1. (canceled)

Claim 2. (currently amended) The method of claim 1 87, wherein the step of determining the maximum tolerated dose comprises performing a dose escalation study for the radiopharmaceutical in a patient population.

Claim 3. (canceled)

Claim 4. (canceled)

Claim 5. (currently amended) The method of claim 1 87, wherein the maximum effective mass is based on the gender and height of the patient.

Claim 6. (currently amended) The method of claim 1 87, wherein the step of determining the clearance profile comprises performing a study following measurement over time of the loss of radioactivity from an administered radiopharmaceutical.

Claim 7. (currently amended) The method of claim 1 87, wherein the step of determining the clearance profile comprises performing a dose escalation study for the radiopharmaceutical.

Claim 8. (currently amended) The method of claim 1 87, wherein the clearance profile provides an activity-time curve shape for the radiopharmaceutical.

Claim 9. (canceled)

Claim 10. (currently amended) The method of claim ~~4~~ 87, wherein the step of determining the residence time for the radiopharmaceutical comprises:

making measurements of radioactivity in the whole body of the patient at each of a number of time points,

calculating percent injected activity of the radiopharmaceutical at each of the time points, and

establishing the residence time by plotting the time points vs. percent injected activity on a semilog graph and determining the time at 37% injected activity.

Claim 11. (original) The method of claim 10, wherein each time point is background corrected.

Claim 12. (original) The method of claim 10, wherein the number of time points are correlated to the clearance profile of the radiopharmaceutical so that at least 2 measurements are made if the radiopharmaceutical has monoexponential clearance, at least 4 measurements are made if the radiopharmaceutical has biexponential clearance, and at least 6 measurements are made if the radiopharmaceutical has triexponential clearance.

Claim 13. (canceled)

Claim 14. (currently amended) The method of claim ~~13~~ 89, wherein each time point is background corrected.

Claim 15. (canceled)

Claim 16. (currently amended) The method of claim ~~15~~ 90, wherein each time point is background corrected.

Claim 17. (currently amended) The method of claim ~~15~~ 90, wherein the number of time points are correlated to the clearance profile of the radiopharmaceutical so that at least 2 measurements are made if the radiopharmaceutical has monoexponential clearance, at

least 4 measurements are made if the radiopharmaceutical has biexponential clearance, and at least 6 measurements are made if the radiopharmaceutical has triexponential clearance.

Claim 18. (currently amended) The method of claim 1 87, wherein the step of determining the residence time for the radiopharmaceutical comprises:

making measurements of radioactivity in the whole body of the patient at each of a number of time points, generating an activity-time curve, and using the trapezoidal rule or Simpson's rule to determine the residence time.

Claims 19-22 (canceled)

Claim 23. (currently amended) The method of claim ~~22~~ 93, wherein each time point is background corrected.

Claim 24. (currently amended) The method of claim ~~22~~ 93, wherein the number of time points are correlated to the clearance profile of the radiopharmaceutical so that at least 2 measurements are made if the radiopharmaceutical has monoexponential clearance, at least 4 measurements are made if the radiopharmaceutical has biexponential clearance, and at least 6 measurements are made if the radiopharmaceutical has triexponential clearance.

Claims 25-84 (canceled)

Claim 85. (currently amended) The method of claim 1 87, wherein said maximum effective mass is a multiple of a calculated lean body mass, said multiple having been determined from empirical data gathered from dose escalation studies in a patient population to which said patient ~~would belong~~ belongs.

Claim 86. (previously presented) The method of claim 85, wherein said multiple is 1.37.

Claim 87. (new) A method of establishing a patient-specific therapeutic dose for administration of an ^{131}I -labeled anti-B1 antibody radiopharmaceutical to a patient, the method comprising:

- determining a maximum tolerated dose for the radiopharmaceutical;
- determining a desired total body dose (TBD) of the radiopharmaceutical for the patient;
- administering to the patient a trace dose of a radiopharmaceutical or an analog of the radiopharmaceutical;
- determining a clearance profile for the radiopharmaceutical or the radiopharmaceutical analog;
- determining the patient's mass and maximum effective mass;
- selecting the lower of the patient's mass and maximum effective mass;
- determining activity hours (AH) for the radiopharmaceutical or radiopharmaceutical analog by reference to Equation I:

$$AH = \frac{TBD \times (M \text{ or } MEM)}{\left[\sum_{elec} \Delta_{elect} + \sum_{phot} \Delta_{phot} \phi^{TB}_{phot} \right]}$$

(Equation I)

where $\left[\sum_{elec} \Delta_{elect} + \sum_{phot} \Delta_{phot} \phi^{TB}_{phot} \right]$

in Equation I represents the sum of electron energy and photon energy deposited in the total body of the patient by the radiopharmaceutical or radiopharmaceutical analog and said determining activity hours uses the lower of the patient's mass (M) or maximum effective mass (MEM);

determining residence time of an administered tracer dose of the radiopharmaceutical or the radiopharmaceutical analog in the whole body of the patient, the residence time being correlated to the clearance profile; and

establishing the patient-specific dose of the radiopharmaceutical for the patient by solving for therapeutic dose in the following equation:

$$\text{therapeutic dose} = \frac{\text{Activity Hours}}{\text{Residence time}} \times \frac{\text{desired total body dose}}{\text{maximum tolerated dose.}}$$

Claim 88. (new) The method of claim 87, wherein reference to Equation I comprises obtaining activity hours from a table or database that has been prepared using Equation I

Claim 89. (new) The method of claim 87, wherein the step of determining the residence time for the radiopharmaceutical comprises:

making measurements of radioactivity in the whole body of the patient at each of three time points and solving for residence time in the following equation:

$$\text{Residence time (hr)} = \frac{t_2 (1 - \frac{c_2}{c_1})}{\log_e (\frac{c_1}{c_2})} + \frac{\frac{c_2}{c_1} (t_3 - t_2)}{\log_e (\frac{c_2}{c_3})}$$

where t_1 , t_2 , and t_3 are the three time points and c_1 , c_2 , and c_3 are the counts at each of the t_1 , t_2 , and t_3 time points.

Claim 90. (new) The method of claim 87, wherein the step of determining the residence time for the radiopharmaceutical comprises:

making measurements of radioactivity in the whole body of the patient at each of a number of time points, and solving for τ in the following equation:

$$\tau = \frac{\sum_{i=1}^n \frac{a_i}{\alpha_i}}{\sum_{i=1}^n a_i}$$

where τ is residence time, n is the number of exponential terms as determined by the clearance profile, a_i are the intercepts, and α_i are the slopes of the i th exponential term when plotted on a log-linear graph with percent injected activity plotted on the y-axis and time on the x-axis.

Claim 91. (new) An ^{131}I -labeled anti-B1 antibody radiopharmaceutical composition ready for administration to a patient, comprising a predetermined amount of said ^{131}I -

labeled anti-B1 antibody in a pharmaceutical carrier, wherein said amount is determined by the method comprising:

- determining a maximum tolerated dose for the radiopharmaceutical;
- determining a desired total body dose of the radiopharmaceutical for the patient;
- administering to the patient a trace dose of a radiopharmaceutical or an analog of the radiopharmaceutical;
- determining a clearance profile for the radiopharmaceutical or the radiopharmaceutical analog;
- determining the patient's mass and maximum effective mass;
- selecting the lower of the patient's mass and maximum effective mass;
- determining activity hours (AH) for the radiopharmaceutical or radiopharmaceutical analog by reference to Equation I:

$$AH = \frac{TBD \times (M \text{ or } MEM)}{\left[\sum_{elec} \Delta_{elect} + \sum_{phot} \Delta_{phot} \phi^{TB}_{phot} \right]}$$

(Equation I)

where $\left[\sum_{elec} \Delta_{elect} + \sum_{phot} \Delta_{phot} \phi^{TB}_{phot} \right]$

in Equation I represents the sum of electron energy and photon energy deposited in the total body of the patient by the radiopharmaceutical or radiopharmaceutical analog, wherein said determining uses the lower of the patient's mass (M) or maximum effective mass (MEM) and the desired total body dose (TBD);

determining residence time of an administered tracer dose of the radiopharmaceutical or the radiopharmaceutical analog in the whole body of the patient, the residence time being correlated to the clearance profile; and

establishing the patient-specific dose of the radiopharmaceutical for the patient by solving for therapeutic dose in the following equation:

$$\text{therapeutic dose} = \frac{\text{Activity Hours}}{\text{Residence time}} \times \frac{\text{desired total body dose}}{\text{maximum tolerated dose.}}$$

Claim 92. (new) A method of establishing a patient-specific dose for administration of an ^{131}I -labeled anti-B1 antibody radiopharmaceutical to a patient, the method comprising:

determining a clearance profile for the radiopharmaceutical or a radiopharmaceutical analog, said clearance profile providing a minimum number of time points for determination of the patient-specific residence time of the radiopharmaceutical or the radiopharmaceutical analog,

determining the desired total body dose (TBD) of the radiopharmaceutical for the patient;

determining the patient's mass (M) and maximum effective mass (MEM);

selecting the lower of the patient's mass and maximum effective mass (M or MEM);

determining activity hours (AH) for the radiopharmaceutical or a radiopharmaceutical analog by reference to Equation I using the lower of the patient's mass and maximum effective mass (M or MEM):

$$AH = \frac{TBD \times (M \text{ or } MEM)}{\left[\sum_{elec} \Delta_{elec} + \sum_{phot} \Delta_{phot} \phi_{phot}^{TB} \right]}$$

(Equation I)

where $\left[\sum_{elec} \Delta_{elec} + \sum_{phot} \Delta_{phot} \phi_{phot}^{TB} \right]$

in Equation I represents the sum of electron energy and photon energy deposited in the total body of the patient by the radiopharmaceutical or radiopharmaceutical analog;

determining the patient-specific residence time of an administered tracer dose of the radiopharmaceutical or the radiopharmaceutical analog in the whole body of the patient; and

establishing a therapeutic dose of the radiopharmaceutical for the patient by dividing the activity hours by the patient-specific residence time to obtain an initial therapeutic dose and optionally multiplying the initial therapeutic dose by an attenuation factor, said attenuation factor being determined by the TBD divided by the maximum tolerated dose for the radiopharmaceutical.

Claim 93. (new) The method of claim 92, wherein the step of determining the residence time for the radiopharmaceutical comprises:

making measurements of radioactivity in the whole body of the patient at each of a number of time points, and solving for τ in the following equation:

$$\tau = \frac{\sum_{i=1}^n \frac{a_i}{\alpha_i}}{\sum_{i=1}^n a_i}$$

where τ is residence time, n is the number of exponential terms as determined by the clearance profile, a_i are the intercepts, and α_i are the slopes of the i th exponential term when plotted on a log-linear graph with percent injected activity plotted on the y-axis and time on the x-axis.